



INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet	1	of	2
-------	---	----	---

Complete if Known

Application Number	10/644,256
Filing Date	August 20, 2003
First Named Inventor	Jones et al.
Group Art Unit	To be assigned 1636 <i>WLF</i>
Examiner Name	To be assigned SCHLAPKOHL <i>WLF</i>
Attorney Docket Number	2578-6077US

U.S. PATENT DOCUMENTS

[illegible]

FOREIGN PATENT DOCUMENTS

[illegible]

**Examiner
Signature**

Wm. Chapkoff

Date Considered

3-13-2006

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Substitute for form 1449A/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Application Number	10/644,256
		Filing Date	August 20, 2003
		First Named Inventor	Jones et al.
		Group Art Unit	To be assigned 1636 WRL
		Examiner Name	To be assigned SCHLAPKOHLE WRL
		Attorney Docket Number	2578-607711S
Sheet	2	of	2

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
WRL		#GHOSH-CHOUDHURY et al., Protein IX, a minor component of the human adenovirus capsid, is essential for the packaging of the full length genomes, The EMBO Journal, 1987, pp. 1733-39, Vol. 6, No. 6.	
WRL		#LOUIS et al., Cloning and Sequencing of the Cellular-Viral Junctions from the Human Adenovirus Type 5 Transformed 293 Cell Line, Virology, 1997, pp. 423-29, Vol. 233.	
WRL		#NCBI Entrez Nucleotide accession number U38242.	
WRL		#NCBI Entrez Nucleotide accession number NC_002018.	
WRL		#NCBI Entrez Nucleotide accession number X02996 J01967 J01968 J01970 J01971 J01972 J01974 J01976 J01977 J01978 J01979 K00515 V00025 V00026 V00027 V00029.	
WRL		#SETOGUCHI et al., "Stimulation of Erythropoiesis by in vivo gene therapy: Physiologic consequences of transfer of the humanerythropoietin gene to experimental animals using an adenovirus vector," Blood, November 1, 1994, pp. 2946-53, Vol. 84, No. 9.	

Examiner Signature	WRL Schlapkohl	Date Considered	3-13-2006
-----------------------	----------------	--------------------	-----------

Pursuant to 37 C.F.R. § 1.98(d), copies of the previously identified patents are not being provided since they were previously cited by or submitted to the Office in the following prior application:

Serial No.: 09/549,463

Filed: April 14, 2000

For: RECOMBINANT PROTEIN PRODUCTION IN A HUMAN CELL, which application is being relied upon for an earlier filing date under 35 U.S.C. § 120.

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Complete if Known

Application Number	10/644,256
Filing Date	August 20, 2003
First Named Inventor	Jones et al.
Group Art Unit	1632
Examiner Name	W. Schlapkohl,
Attorney Docket Number	2578-6077US

(use as many sheets as necessary)

Sheet	1	of	5
-------	---	----	---

[illegible][illegible]

And Joseph

3-12-2006

¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet

2

of

5

Complete if Known

Application Number	10/644,256
Filing Date	August 20, 2003
First Named Inventor	Jones et al.
Group Art Unit	1632
Examiner Name	W. Schlapkohl, Ph.D.
Attorney Docket Number	2578-6077US

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
msf		ALKHATIB et al., "Expression of Bicistronic Measles Virus P/C mRNA by Using Hybrid Adenovirus: Levels of C Protein Synthesized In Vivo Are Unaffected by the Presence or Absence of the Upstream P Initiator Codon," Journal of Virology, November 1988, pp. 4059-4068, Vol. 62, No. 11.	
msf		ALKHATIB et al., "High-Level Eucaryotic In Vivo Expression of Biologically Active Measles Virus Hemagglutinin by Using an Adenovirus Type 5 Helper-Free Vector System," Journal of Virology, August 1988, pp. 2718-2727, Vol. 62, No. 8.	
msf		BERG et al., High-Level Expression of Secreted Proteins from Cells Adapted to Serum-Free Suspension Culture, Research Report, BioTechniques, 1993, pp. 972-78, Vol. 14, No. 6.	
msf		BROWN et al., "Evaluation of Cell Line 293 for Virus isolation in Routine Viral Diagnosis," Journal of Clinical Microbiology, April 1986, pp. 704-708, Vol. 23, No. 4.	
msf		BUKREYEV et al., "Recombinant Respiratory Syncytial Virus from Which the Entire SH Gene Has Been Deleted Grows Efficiently in Cell Culture and Exhibits Site-Specific Attenuation in the Respiratory Tract of the Mouse," Journal of Virology, December 1997, pp. 8973-8982, Vol. 71, No. 12.	
msf		CARAVOKYRI et al., "Constitutive Episomal Expression of Polypeptide IX (pIX) in a 293-Based Cell Line Complements that Deficiency of pIX Mutant Adenovirus Type 5," Journal of Virology, November 1995, pp. 6627-6633, Vol. 69, No. 11.	
msf		Certificate of deposit of the PER.C6 cell line (ECACC deposit under number 96022940).	
msf		CICCARONE et al., "Lipofectamine 2000 Reagent for Transfection of Eukaryotic Cells," Focus, 1999, pp. 54-55, Vol. 21, No. 2.	
msf		COTE et al., Serum-Free Production of Recombinant Proteins and Adenoviral Vectors by 293SF-3F6 Cells, Biotechnology and Bioengineering, September 5, 1998, pp. 567-75, Vol. 59, No. 5.	
msf		DuBRIDGE et al., "Analysis of Mutation in Human Cells by Using an Epstein-Barr Virus Shuttle System," Molecular and Cellular Biology, January 1987, pp. 397-387, Vol. 7, No. 1.	
msf		ENDO et al., Growth of Influenza A Virus in Primary, Differentiated Epithelial Cells Derived from Adenoids, Journal of Virology, Mar. 1996, pp. 2055-58, Vol. 70, No. 3.	
msf		FALLAUX et al., Characterization of 911: A New Helper Cell Line for the Titration and Propagation of Early Region 1- Deleted Adenoviral Vectors, Human Gene Therapy, January 20, 1996, pp. 215-222, Vol. 7.	

Examiner Signature	<i>W. Schlapkohl</i>	Date Considered	3-12-2006
--------------------	----------------------	-----------------	-----------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 3 of 5

Complete if Known

Application Number	10/644,256
Filing Date	August 20, 2003
First Named Inventor	Jones et al.
Group Art Unit	1632
Examiner Name	W. Schlapkohl, Ph.D.
Attorney Docket Number	2578-6077US

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
Wdf		Figure 1 submitted by Opponent I.	
Wdf		GALLIMORE et al., Transformation of Human Embryo Retinoblasts with Simian Virus 40, Adenovirus and ras Oncogenes, Anticancer Research, 1986, pp. 499-508, Vol. 6.	
Wdf		GARNIER et al., Scale-up of the adenovirus expression system for the production of recombinant protein in human 293S cells, Cytotechnology, 1994, pp. 145-55, Vol. 15.	
Wdf		GenBank Accession No. X02996.1, 1993, "Adenovirus type 5 left 32% of the genome."	
Wdf		GIBCO cell culture, A Guide to Serum-Free Cell Culture, www.invitrogen.com.	
Wdf		GRAHAM et al., "Characteristics of a Human Cell Line Transformed by DNA from Human Adenovirus Type 5," J. Gen. Virol., 1997, pp. 59-72, Vol. 36.	
Wdf		GRAHAM et al., "Growth of 293 cells in suspension culture," J Gen Virol, March 1987, pp. 937-940, Vol. 68.	
Wdf		GRAHAM, Cell Lines, Promochem (visited 04.10.2005) <http://www.lgcpromochem-atcc.com/SearchCatalogs/longview.cfm?view=ce,1146678...>.	
Wdf		HOLZER et al., "Construction of a Vaccinia Virus Deficient in the Essential DNA Repair Enzyme Uracil DNA Glycosylase by a Complementing Cell Line," Journal of Virology, July 1997, pp. 4997-5002, Vol. 71, No. 7.	
Wdf		INOUE et al., Production of Recombinant Human Monoclonal Antibody Using ras-Amplified BHK-21 Cells in a Protein-free Medium, Biosci. Biotech. Biochem., 1996, pp. 811-17, Vol. 60, No. 5.	
Wdf		Interlocutory Decision of the Opposition Division of 21 July 2003 in the case EP 0 695 351(European application 94 913 174.2)	

Examiner Signature	Wdf/Schlapkohl	Date Considered	3-12-2006
-----------------------	----------------	--------------------	-----------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 4 of 5

Complete if Known

Application Number	10/644,256
Filing Date	August 20, 2003
First Named Inventor	Jones et al.
Group Art Unit	1632
Examiner Name	W. Schlapkohl, Ph.D.
Attorney Docket Number	2578-6077US

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
msf		LOPEZ et al., Efficient production of biologically active human recombinant proteins in human lymphoblastoid cells form integrative and episomal expression vectors, Gene, 1994, pp. 285-91, Vol. 148.	
msf		LUTZ et al., "The Product of the Adenovirus Intermediate Gene IX Is a Transcriptional Activator," Journal of Virology, July 1997, pp. 5102-5109, Vol. 71, No. 7.	
msf		MANSERVIGI et al., "Protection from Herpes Simplex Virus Type 1 Lethal and Latent Infections by Secreted Recombinant Glycoprotein B Constitutively Expressed in Human Cells with a BK Virus Episomal Vector," Journal of Virology, January 1990, pp. 431-436, Vol. 64, No.1.	
msf		Marketing Authorization and Scientific Discussion for Xigris.	
msf		MASSIE et al., Improved Adenovirus Vector Provides Herpes Simplex Virus Ribonucleotide Reductase R1 and R2 Subunits Very Efficiently, Biotechnology, June 1995, pp. 602-08, Vol. 13.	
msf		MERTEN et al., Production of Influenza Virus in Cell Cultures for Vaccine Preparation, Exp Med Biol., 1996, pp. 141-51, Vol. 397.	
msf		NEUMANN et al., "Generation of influenza A viruses entirely from cloned cDNAs," Proc. Natl. Acad. Sci., August 1999, pp. 9345-9350, Vol. 96.	
msf		Notice of Opposition to a European Patent for 1 161 548 by Seroxo.	
msf		Opposition against European patent 1 108 878 B1 filed October 5, 2005 in the name and on behalf of CEVEC Pharmaceuticals GmbH.	
msf		Opposition against European patent 1 161 548 B1 filed November 16, 2005, in the name and on behalf of CEVEC Pharmaceutical GmbH.	
msf		Opposition against European patent 1 108 787 filed October 5, 2005 in the name and on behalf of Probiogen AG.	
msf		ORY et al., "A stable human-derived packaging cell line for production of high titer retrovirus/vesicular stomatitis virus G pseudotypes," Proc. Natl. Acad. Sci., October 1996, pp. 11400-11406, Vol. 93.	

Examiner Signature	<i>msf/schlapkohl</i>	Date Considered	3-12-2006
--------------------	-----------------------	-----------------	-----------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet

5

of

5

Complete if Known

Application Number	10/644,256
Filing Date	August 20, 2003
First Named Inventor	Jones et al.
Group Art Unit	1632
Examiner Name	W. Schlapkohl, Ph.D.
Attorney Docket Number	2578-6077US

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
<i>WLF</i>		PARKINSON et al., "Stable Expression of a Secretable Deletion Mutant of Recombinant Human Thrombomodulin in Mammalian Cells," The Journal of Biological Chemistry, 25 July 1990, pp. 12602-12610, Vol. 265, No. 21.	
<i>WLF</i>		PAUL et al., Increased Viral Titer Through Concentration of Viral Harvests from Retroviral Packaging Lines, Human Gene Therapy, 1993, pp. 609-15, Vol. 4.	
<i>WLF</i>		PLESCHKA et al., "A Plasmid-Based Reverse Genetics System for Influenza A Virus," Journal of Virology, June 1996, pp. 4188-4192, Vol. 70, No. 6.	
<i>WLF</i>		PubMed listing of abstracts (visited 04.10.2005) < http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?CMD=search&DB=pubmed >	
<i>WLF</i>		REINA et al., Comparison of Madin-Darby Canine Kidney cells (MDCK) with a Green Monkey Continuous Cell Line (Vero) and Human Lung Embryonated Cells (MRC-5) in the Isolation of Influenza A Virus from Nasopharyngeal Aspirates by Shell Vial Culture, Journal of Clinical Microbiology, July 1997, pp. 1900-01, Vol. 35, No. 7.	
<i>WLF</i>		RHIM et al., "Development of Human Cell Lines from Multiple Organs," Annals of the New York Academy of Sciences, 2000, pp. 16-25, Vol. 919.	
<i>WLF</i>		SPECTOR et al., "Regulation of Integrated Adenovirus Sequences During Adenovirus Infection of Transformed Cells," Journal of Virology, December 1980, pp. 860-871, Vol. 36, No. 3.	
<i>WLF</i>		STEVENS et al., "The N-Terminal Extension of the Influenza B Virus Nucleoprotein Is Not Required for Nuclear Accumulation or the Expression and Replication of a Model RNA," Journal of Virology, June 1998, pp. 5307-5312, Vol. 72, No. 6.	
<i>WLF</i>		U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, Center for Biologics Evaluation and Research, International Association for Biologicals, National Institute of Allergy and Infectious Diseases, National Vaccine Program Office, World Health Organization, Evolving Scientific and Regulatory Perspectives on Cell Substrates for Vaccine Development, Workshop, Friday, 10 September 1999 (visited 30.09.2005) < http://www.fda.gov/cber/minutes/0910evolvt.txt >	
<i>WLF</i>		YAN et al., Novel Asn-linked oligosaccharides terminating in GalNAc β (1-4)[Fuc α (1-3)]GlcNAc β (1-) are present in recombinant human Protein C expressed in human kidney 293 cells, Glycobiology, 1993, pp. 597-608, Vol. 3, No. 6.	
<i>WLF</i>		YEAGER et al., Constructing immortalized human cell lines, Current Opinion Biotechnology, 1999, pp. 465-69, Vol. 10.	
<i>WLF</i>		YEH et al., Adenoviral Vectors, pp. 25-42 of "Concepts in Gene Therapy," Publisher: Walter de Gruyter, New York.	
Examiner Signature	<i>WLF/Schlapkohl</i>		Date Considered
			3-12-2006

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.